REMARKS

Introductory Remarks

Claims 1-74 are pending in the application. Claims 1-30 and 60-74 are withdrawn from further consideration without prejudice. Therefore, claims 31-59 remain under consideration. Herein Applicants present no new claims, amend no claims, and cancel no claims.

Claim 31 is amended to recite "about 25 mg/mL to about 200 mg/mL", in order to more particularly point out and distinctly claim the invention. Support for the amendment is found, at least, at page 37, paragraphs [0159] to [0162], Figures 2A-2C, and Table II of the Specification.

Rejection under 35 U.S.C. 102(b)

The Office Action has rejected claims 31-59 under 35 U.S.C. 102(b) as allegedly being anticipated by Andya et al. (U.S. Patent No. 6,267,958).

The rejection is respectfully traversed in view of the following remarks.

The standard for anticipation is rigorous requiring that every element of the claimed invention be disclosed by a single prior art reference. *See Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc.*, 976 F.2d 1559, 1565 (Fed.Cir.1992); *Scripps*, 927 F.2d at 1576-77; *Lindemann Maschinenfabrik GMBH, v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed.Cir.1984).

The Office Action by states that the "patentability of the product does not depend on its method of production." Citing Andya et al. at claims 1-8 and 47 and column 17, lines 1-40, in particular, the Examiner alleges that the claimed antibody formulation and the referenced antibody formulation both comprise an antibody, diluent, buffer and sucrose as an excipient. The Examiner concludes that the "characteristics "being visually clear upon reconstitution within about 10min" is inherent property of the claimed and the referenced antibody formulations."

In response, Applicants point out that the claims do not simply recite a reconstituted composition being "visually clear upon reconstitution." Instead, the claims recite (among other things) that the reconstituted composition "is a visually clear reconstituted composition within about 10 minutes of being formed." Emphasis added. In view of the different reconstitution times associated with the lyophilized formulations shown in the specification at paragraph **[0162]** (which are also of the type disclosed in Andya et al.) and the spray dried formulations encompassed by the

claims, it simply cannot be said that a visually clear reconstituted composition within about 10 minutes of being formed is "an inherent property of antibody formulations" generally.

Again, Applicants emphasize that their claims require a reconstituted composition having the feature of visual clarity within about 10 minutes of being formed. Applicants have specifically demonstrated that reconstituted lyophilized compositions -- such as the type disclosed in Andya et al. -- will not inherently become a visually clear reconstituted composition within about 10 minutes of being formed. Further, a close reading of Andya et al. only reveals that the "time required for reconstitution will depend, e.g., on the type of diluent, amount of excipient(s) and protein." See Andya et al. at Column 17, lines 23-25. In addition, Andya et al. fails to disclose the feature of a spray-dried powder, a feature recited in the only pending independent claim. Consequently, as the cited art fails to teach each and every feature recited in the claims, the rejection of claims 31-59 under 35 U.S.C. 102(b) should be removed. Reconsideration and removal of the rejection are respectfully requested.

Rejection under 35 U.S.C. 112, First Paragraph

The Office Action has rejected claims 31-59 under 35 U.S.C. §112, first paragraph, as allegedly introducing New Matter. The Office Action alleges that the phrase "about 25 mg/ml to about 200 mg/ml", is not supported by the specification as filed (citing page 22, lines 1-2 of the specification). Applicants respectfully traverse the rejection for the following.

The Office Action is ignoring the language of the rest of the sentence. The sentence reads:

> "Another preferred range of the antibody is from about 25 mg/mL to about 250 mg/mL".

The Applicants here are describing a range, which sets a boundary for what is within the range. A range encompasses all variables that are within that range. A range is not its edges only. Applicants submit that all of the concentrations between about 25 mg/mL to about 250 mg/mL are encompassed and that Applicants could choose any concentration between these limitations to write their claims.

Further, Applicants had also provided support for the amendment by pointing to several places in the specification. Applicants reproduce the language from the response dated 30 May 2007, below:

> Claim 31 is amended to recite "about 25 mg/mL to about 200 mg/mL", in order to more particularly point out and distinctly claim the invention. Support for the amendment is found, at least, at page 37, paragraphs [0159] to [0162], Figures 2A-2C, and Table II of the Specification.

Applicants submit that in view of the foregoing the amendments to claim 31 are appropriate, and respectfully submit that rejection based on 35 USC 112, paragraph 1 should be withdrawn.

CONCLUSION

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 631-3286.

Respectfully submitted,

Date: 29 November 2007 By: _____

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